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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/554,703 | Applicant(s) LANG-FUGMANN, SUSANNE | |
| | Examiner TIGABU KASSA | Art Unit 1619 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6 and 9-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4, 6, and 9-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>10/06/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the amendment filed August 28, 2009. **Claims 1-2, 4, 6, and 9-15 are pending. Claims 1-2, 4, 6, and 9-15 are under consideration in the instant office action.** Claims 3, 5, and 7-8 are cancelled.

Request for continued examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/06/09 has been entered.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 10/06/09 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the references.

Withdrawn rejections

Applicant's amendments and arguments filed on 10/06/09 are acknowledged and have been fully considered. All rejections applied in the previous office action are hereby withdrawn as a result of applicants claim amendments.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claim 15 is vague and indefinite because a claim cannot depend on itself.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

Claims 1-2, 6, and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samour et al. (US Patent No. 6,224,887) in view of Ippen et al. (US Patent No. 4,956,370).

Applicant Claims

Instant claims 1 and 2 recite a pharmaceutical, antimycotically active nail lacquer for the treatment or prophylaxis of fungal infections of nails and skin comprising an optionally substituted 2-aminothiazole, wherein the nail lacquer further comprising a permeation enhancer, a polymeric film-forming agent, a volatile solvent, a plasticizer, such that the nail lacquer, when applied to a nail, forms an adhered, waterproof film from which the optionally drug is released so as to penetrate the nail. Instant claim 6 recites the pharmaceutical antimycotically active nail lacquer according to claim 1 or 2 characterized in that the film-forming agent belongs to the group of water-insoluble acrylate polymers or methacrylate polymers and comprises a copolymer that belongs to the compound class of alkylvinylethers, maleic acid anhydride, alkylated poly(vinylpyrrolidones) and ammonium methacrylates, respectively Instant claims 9 recites pharmaceutical, antimycotically active nail lacquer according to claim 1 or 2 characterized in that it also comprises a solvent from the list recited in instant claim 9. Instant claim 10 recites the different % by weight amounts of various components of the pharmaceutical, antimycotically active nail lacquer. Instant claim 11 recites that the antimycotically active ingredient in the

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composition is Abafungin. Instant claims 12 and 13 recite a method for the treatment and prophylaxis of fungal infections respectively.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Samour et al. teach an antifungal nail lacquer comprising permeation (penetration) enhancing agent (column 3, lines 19-21) and polymeric film-forming agent (column 3, line 23). For the types of film forming agents Samour et al. also teach that film forming agents can include acrylate (co)polymers, methacrylate (co)polymers, and copolymers of alkyl vinyl ether and maleic anhydride (column 6, line 38-40)

Samour et al. teach an antifungal nail lacquer comprising 5-20 % of an antifungal active agent, (column 12, line 25-26), 0.5-35 % enhancer (column 5, line 26), 20-40 % film forming polymer (column 8, line 43), 53% ethanol (column 16, line 55-56), and 2-10% plasticizer (column 9, line 23).

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Although Samour et al. teach the incorporation of an antifungal agent in the antifungal based nail lacquer composition, Samour et al. do not explicitly teach the substituted 2-aminothiazole as the antifungal agent type. This deficiency is cured by the teachings of Ippen et al.

Ippen et al. disclose a pharmaceutical composition useful for combating mycoses comprising substituted 2-aminothiazole and other pharmaceutical excipients (column 1, lines 20-68, column 2, lines 1-21, column 146, line 46-49, and see Abstract). Ippen et al. disclose that the

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pharmaceutical preparation could be in the form of tablets, coated tablets, capsules, pills, granules, suppositories, solutions, suspensions, emulsions, pastes, ointments, gels, creams, lotions, powders, or sprays (column 19, lines 62-66). It is examiner's position that the pharmaceutical composition described by Ippen et al. as being able to be prepared in various forms, are capable of being nail lacquer compositions.

Ippen et al. disclose the pharmaceutical composition also comprises a plasticizer such as polyethylene glycols (column 20, line 30), solvents like water, ethyl alcohol, isopropyl alcohol, ethyl acetate etc (column 20, lines 48-51).

Ippen et al. also disclose, in the examples section, the use of Abafungin (Table A column 141, compound 149) in *in vitro* activity test, which is the structure of Abafungin, which addresses instant claim 11.

Ippen et al. teach that the pharmaceutical composition can be used for the treatment, prevention, amelioration and/or cure of mycoses (column 21, lines 26-27) either dermatomycoses and systemic mycoses (column 19, lines 32-33) (which includes nails). Specifically, Ippen et al. disclose a method of combating mycoses through administering the above disclosed pharmaceutical composition (column 146, lines 54-58).

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of Samour et al. via the incorporation of substituted 2-aminothiazole as antifungal agent, because Ippen et al. teach substituted 2-aminothiazole as antifungal agent useful for combating mycoses comprising substituted 2-aminothiazole and other pharmaceutical excipients (column 1, lines 20-68, column 2, lines 1-21,

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column 146, line 46-49, and see Abstract) . It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute the antifungal agent taught by Samour et al. with substituted 2-aminothiazole which is another antifungal agent taught by Ippen et al. because both antifungal agents are functionally equivalent. The skilled artisan would have been motivated to substitute one antifungal agent with another because both agents can exert the desired therapeutic effect namely combating mycoses or fungal infections. The skilled artisan would have had a reasonable expectation of success in combining Samour et al. and Ippen et al., because Ippen et al. teach that the pharmaceutical composition can be used for the treatment prevention, amelioration and/or cure of mycoses (column 21, lines 26-27) either dermatomycoses and systemic mycoses (column 19, lines 32-33), which includes nails and also Samour et al. teach a nail lacquer composition.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1-2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samour et al. (US Patent No. 6,224,887) in view of Ippen et al. (US Patent No. 4,956,370) and Wohlrab et al. (US Patent No. 6,719,986).

Applicant Claims

The claimed subject matter of instant claims 1-2 are set forth above. Instant claim 4 requires hyaluronate lyase as permeation enhancer agent.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Samour et al. and Ippen et al. are set forth above.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Samour et al. and Ippen et al. do not teach in the incorporation of hyaluronate lyase as the permeation enhancing agent. This deficiency is cured by the teaching of Wohlrab et al..

Wohlrab et al. teach hyaluronate lyase as a penetration enhancing agent in topical agents (see Abstract).

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of Samour et al. and Ippen et al. by incorporating hyaluronate lyase, because Wohlrab et al. teach the use of hyaluronate lyase as permeation enhancing agent in topical agents. The skilled artisan would have been motivated to incorporate the permeation enhancer hyaluronate lyase, because Wohlrab et al. teach that it has been known for a long time that through the presence of one or more special auxiliary substances such as hyaluronate lyase the penetration of active agents can be made easier and modulated (column 1, lines 32-35). The skilled artisan would have had a reasonable expectation of success in combining Samour et al., Ippen et al., and Wohlrab et al., because all the three references teach the delivery of agents topically.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1-2, 11, and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samour et al. (US Patent No. 6,224,887) in view of Ippen et al. (US Patent No. 4,956,370) and Gyurik (WO 01/60325, IDS reference).

Applicant Claims

The claimed subject matter of instant claims 1-2 and 11 are set forth above. Instant claim 14 recites a pharmaceutical, antimycotically active nail lacquer according to claim 11 wherein the permeation enhancer comprises oxacyclohexadecan-2-one; wherein the film-forming agent comprises an amine or quaternary ammonium group containing acrylic acid copolymer; wherein the volatile solvent comprises ethanol; and wherein the plasticizer comprises propylene glycol. Instant claim 15 recites a pharmaceutical, antimycotically active nail lacquer, wherein the 2-aminothiazole is present in 2 wt%, oxacyclohexadecan-2-one is 15 wt %; wherein the amine or quaternary ammonium group containing acrylic acid copolymer is 15 wt%; wherein the volatile solvent comprises ethanol is 60 wt%; and wherein the plasticizer comprises propylene glycol is 5 wt%, and further comprising 3 wt% of water.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Samour et al. and Ippen et al. are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Although Samour et al. teach a nail lacquer composition comprising antifungal agent, film forming polymer, solvent, permeation enhancer and plasticizer; and the amounts of each component, Samour et al. do not explicitly teach the specific types of film forming polymer, permeation enhancer, plasticizer and their amounts as recited in instant claims 14 and 15 respectively. This deficiency is cured by the teachings of Gyurik.

Note: The antifungal agent substituted 2-aminothiazole is addressed by the teachings of Ippen et al.

Gyurik teaches an illustrative example of a nail lacquer composition comprising clotrimazole 4 wt%, Eudragit RL 100 powder (ethyl acrylate, methyl methacrylate, trimethylammoniummethyl methacrylate copolymer) 15 wt%, oxacyclohexadecan-2-one 15 wt%, propylene glycol 5 wt%, ethanol 58 wt%, and water 3 wt% (page 16, example 1, lines 14-21).

Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of Samour et al. and Ippen et al. by incorporating the specific types of film forming polymer, permeation enhancer, plasticizer, and solvent and their amounts as recited in instant claims 14 and 15, because Gyurik teach exactly the same film forming polymer, permeation enhancer, plasticizer, and solvent and their amounts. However, Gyurik teaches in the above example a different antifungal agent clotrimazole. Ippen et al. already addressed the substituted 2-aminothiazole as the antifungal agent above. The skilled artisan would have been motivated to incorporate the specific types of film forming

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polymer, permeation enhancer, plasticizer, solvent and their amounts as recited in instant claims 14 and 15, because they are conventionally known additives in a nail lacquer composition as also demonstrated by Gyurik. The skilled artisan would have had a reasonable expectation of success in combining Samour et al., Ippen et al., and Gyurik, because all the three references teach the delivery of agents topically.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Claims 1-2, 4, 6, and 9-15 are rejected, while claims 3, 5, 7-8 are cancelled. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne P. Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa

10/12/09

/Mina Haghighatian/

Primary Examiner, Art Unit 1616